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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION, FIELD OPERATIONS BRANCH, COMPLIANCE TEAM

4298 Elysian Fields Avenue
New Orleans, LA 70122
Telephone (504) 589-7166
Fax (504) 589-6360

July 2, 1997

WARNING LETTER NO. 97-NOL-51

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Gene Chrisman, President
Medi-rents and Sales, Inc.
2155 IH-10 East
Beaumont, Texas 77701

Dear Mr. Chrisman:

During an inspection of your facility, Medi-rents and Sales, Inc., located at 1810 E. Prien Lake Road, Suite B, Lake Charles, Louisiana 70601, on June 25 and 26, 1997, our investigator documented deviations from the Current Good Manufacturing Practice Regulations (CGMP's), which cause the medical oxygen transfilled by your facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). In addition, your firm has not registered as a drug manufacturer and listed the drugs manufactured (medical oxygen) with the Food and Drug Administration as required by Section 510 of the Act.

The medical oxygen GMP deviations include:

1. Failure to establish written specifications and scientifically sound and appropriate test procedures for the assay of Oxygen, U.S.P. or to document that U.S.P. testing by the supplier was witnessed by a trained employee [21 CFR 211.160(b)];

2. Failure to properly calibrate the [redacted] Oxygen Analyzer, used for the identity testing of Oxygen, U.S.P., in that your firm did not have a high purity Oxygen reference standard, as required by the device manufacturer [21 CFR 211.160(b)(4)];

3. Failure to document adequate prefill operations on each cryogenic vessel prior to filling with medical oxygen [21 CFR 211.84(d)(3)];

4. Failure to establish written procedures designed to assure that the drug products have the identity and strength they purport or are represented to possess [21 CFR 211.100(a)];

5. Failure to establish a written training program to include GMP training on a continuing basis and with sufficient frequency to assure that employees remain familiar with applicable CGMP requirements [21 CFR 211.25(a)];

This letter will serve as official notice to you that FDA expects all of your firm's locations to be in compliance with the Federal Food, Drug and Cosmetic Act.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for this delay and the time with which the corrections will be completed.

Your response should be directed to Barbara D. Wright, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122, telephone number (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Mrs. Wright.

Sincerely,

Martin Goldstein

James E. Gamet
District Director
New Orleans District

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cc: Mr. Russell K. Benevage, Manager
Medi-rents and Sales, Inc.
1810 E. Prien Lake Rd., Ste. B
Lake Charles, LA 70601

Enclosure: FDA-483
Drug Registration & Listing Booklet
Drug Product Listing Form (FDA 2657)
Drug Registration Form (FDA 2656)